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TITLE 345 INDIANA STATE BOARD OF ANIMAL HEALTH

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## Final Rule

LSA Document #20-476(F)

## DIGEST

Amends [345 IAC 8-2-1.1](#) to add a definition for graded and ungraded milk. Amends [345 IAC 8-2-2.1](#) to add certain manufacturing grade milk plant construction, operation, and sanitation standards. Amends [345 IAC 8-2-3](#) to clarify the standards for the separation of graded and ungraded milk on manufacturing grade dairy farms. Amends [345 IAC 8-3-1](#) to update the incorporation by reference of the Food and Drug Administration (FDA) Grade A Pasteurized Milk Ordinance (PMO) and other FDA food safety regulations. Amends [345 IAC 8-3-2](#) to clarify the standards for the separation of graded and ungraded milk on Grade A dairy farms. Effective 30 days after filing with the Publisher.

[345 IAC 8-2-1.1](#); [345 IAC 8-2-2.1](#); [345 IAC 8-2-3](#); [345 IAC 8-3-1](#); [345 IAC 8-3-2](#)

SECTION 1. [345 IAC 8-2-1.1](#) IS AMENDED TO READ AS FOLLOWS:

**[345 IAC 8-2-1.1](#) Definitions**

**Authority:** [IC 15-17-3-21](#); [IC 15-18-1-14](#)

**Affected:** [IC 15-17-2](#); [IC 15-17-4](#); [IC 16-42](#)

Sec. 1.1. (a) In the interpretation and enforcement of this article, unless the context otherwise requires, the definitions in [IC 15-17-2](#) and the following definitions apply:

(1) "Automatic milking installation" or "AMI" means the entire installation of one (1) or more automatic milking units, including the hardware and software utilized in the operation of:

- (A) individual automatic milking units;
- (B) the animal selection system;
- (C) the automatic milking machine;
- (D) the milk cooling system;
- (E) the system for cleaning and sanitizing the automatic milking unit;
- (F) the teat cleaning system; and
- (G) the alarm systems;

associated with the process of milking, cooling, cleaning, and sanitation.

(2) "Bacterial counts" means:

- (A) bacterial plate counts; and
- (B) plate loop counts;

that, whenever mentioned in dairy product standards of identity, are made according to the methods outlined in the current edition of "Standard Methods for the Examination of Dairy Products", published by the American Public Health Association, and the current edition of Official Methods of Analysis of the Association of Official Analytical Chemists, or such methods that are approved by the board.

(3) "Butter" means the food product usually known as butter and that is made:

- (A) exclusively from milk or cream, or both; and
- (B) with or without:
  - (i) common salt; and
  - (ii) additional coloring matter;

and containing not less than eighty percent (80%) by weight of milk fat, all tolerances having been allowed for.

(4) "Buttermilk" means a fluid product ~~which~~ **that** contains not less than eight and one-fourth percent (8 1/4%) of milk solids not fat and is either a:

- (A) fluid product resulting from the manufacture of butter from milk or cream; or
- (B) Grade A fluid product, also known as "cultured buttermilk", resulting from the pasteurization of milk that is inoculated with an appropriate culture.

Either product may be concentrated (condensed) or dried.

(5) "Buyer of raw milk" means any:

- (A) milk producer marketing organization;
- (B) milk plant;
- (C) receiving station;
- (D) transfer station; or

(E) bulk hauler;  
that takes delivery of raw milk or raw cream and manages the sale of the raw milk or raw cream.

(6) "Cheese" means:

- (A) natural cheeses;
- (B) processed cheeses;
- (C) cheese foods;
- (D) cheese spreads; and
- (E) related foods;

described in the matters incorporated by reference in [345 IAC 8-3-1\(e\)](#).

(7) "Clean" means product and contaminants have been thoroughly and effectively removed from direct and indirect product contact surfaces.

(8) "Concentrated milk" and "condensed milk" means the fluid product:

- (A) that is unsterilized and unsweetened; and
- (B) resulting from the removal of a considerable portion of the water from the milk;

that, when combined with potable water in accordance with instructions printed on the container, results in a product conforming with the milk fat and the milk solids not fat levels of milk defined in this rule.

(9) "Concentrated milk products" and "condensed milk products" means:

- (A) homogenized concentrated milk;
- (B) concentrated nonfat milk;
- (C) concentrated reduced fat or low fat milk; and
- (D) similar concentrated products made from concentrated milk or concentrated nonfat milk;

that, when combined with potable water in accordance with instructions printed on the container, conform with the definitions of the corresponding milk products in this section.

(10) "Cooling pond" means a man-made structure designed for the purpose of cooling lactating hooved mammals.

(11) "Cottage cheese" means the product defined in 21 CFR 133.128.

(12) "Drug" means articles intended:

- (A) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in animals; or
- (B) to affect the structure or any function of the body of animals.

(13) "Dry curd cottage cheese" means the product defined in 21 CFR 133.129.

(14) "Dry milk products" means products resulting from the:

- (A) drying of milk or milk products; or
- (B) combination of dry milk products with other wholesome dry ingredients.

(15) "Eggnog" or "boiled custard" means the product defined in 21 CFR 131.170.

(16) "Farm bulk tank" or "bulk tank" means the refrigerated tank located on a dairy farm in which raw milk is stored before collection by a milk hauler holding a current hauler/sampler permit issued by the board or a state dairy regulatory agency.

(17) "Food allergens" means proteins in foods that are capable of inducing an allergic reaction or response in some individuals. There is scientific consensus that the following foods account for more than ninety percent (90%) of all food allergies:

- (A) Peanuts.
- (B) Soybeans.
- (C) Milk.
- (D) Eggs.
- (E) Fish.
- (F) Crustacea.
- (G) Tree nuts.
- (H) Wheat.

(18) "Frozen desserts" means:

- (A) ice cream;
- (B) frozen custard;
- (C) goat's milk ice cream;
- (D) sherbets;
- (E) mellorine; and
- (F) related foods;

described in the matters incorporated by reference in [345 IAC 8-3-1\(f\)](#).

(19) "Frozen milk concentrate" means a frozen milk product with a composition of milk fat and milk solids that are not fat in such proportions that, when a given volume of concentrate is mixed with a given volume of water, the reconstituted product conforms to the milk fat and the milk solids not fat requirements of whole milk.

(20) "Goat milk" means the normal lacteal secretion, practically free of colostrum, obtained by the complete milking of one (1) or more healthy goats.

(21) "Grade A dry milk and whey products" means products that have been:

- (A) produced for use in Grade A pasteurized or aseptically processed milk products; and
- (B) manufactured under the provisions of [345 IAC 8-3](#).

(22) "Grade A milk plant" means any place, premises, or establishment where Grade A milk products are:

- (A) collected;
- (B) handled;
- (C) processed;
- (D) stored;
- (E) pasteurized;
- (F) bottled; or
- (G) prepared;

for distribution.

(23) "Grade A producer" means a milk producer that is producing and selling Grade A raw milk under a Grade A permit issued by the board.

(24) "Grade A raw milk" means milk that has been produced under a Grade A dairy farm permit pursuant to the provisions set forth at [345 IAC 8-3-2](#).

**(25) "Graded milk" means all milk produced under a permit issued by the board and meeting the standards for either Grade A or manufacturing grade milk.**

~~(25)~~ (26) "Health authority", "board", or "state board" means the Indiana state board of animal health or its authorized representative.

~~(26)~~ (27) "Hooved mammals milk" means the normal lacteal secretion, practically free of colostrum, obtained by the complete milking of one (1) or more healthy hooved mammals. Hooved mammals include, but are not limited to, members of the order Cetartiodactyla, such as the following:

- (A) The family Bovidae (cattle, water buffalo, sheep, goats, yaks).
- (B) The family Camelidae (llamas, alpacas, camels).
- (C) The family Cervidae (deer, reindeer, moose).
- (D) The family Equidae (horses, donkeys).

~~(27)~~ (28) "Industry plant sampler" means an employee of a milk plant, receiving station, or transfer station that is certified by the board and responsible for the collection of official samples for regulatory purposes at a milk plant, receiving station, or transfer station as outlined in the Grade A Pasteurized Milk Ordinance (PMO), Appendix N.

~~(28)~~ (29) "Manufacturing grade milk plant" means any place, premises, or establishment where manufacturing grade milk products are:

- (A) collected;
- (B) handled;
- (C) processed;
- (D) stored;
- (E) pasteurized; or
- (F) prepared;

for distribution.

~~(29)~~ (30) "Manufacturing grade milk products" means milk and milk products processed and packaged in compliance with the standards of this rule but not considered Grade A, such as the following:

- (A) Cheese.
- (B) Frozen desserts.
- (C) Frozen desserts mixes.
- (D) Butter.

~~(30)~~ (31) "Manufacturing grade producer" means a milk producer that has a permit from the board to produce and sell manufacturing grade raw milk.

~~(31)~~ (32) "Manufacturing grade raw milk" means raw milk produced on a dairy farm that has a valid permit issued by the board to sell raw milk for manufacturing grade milk and milk products.

~~(32)~~ (33) "Milk" means the normal lacteal secretion, practically free from colostrum, obtained by the complete milking of one (1) or more healthy:

- (A) cows;
- (B) sheep;
- (C) goats;
- (D) water buffalo; or
- (E) hooved mammals.

~~(33)~~ (34) "Milk plant" means a Grade A milk plant or a manufacturing grade milk plant. For the purposes of the matters incorporated by reference at [345 IAC 8-3-1\(a\)](#), however, "milk plant" means a Grade A milk plant only.

~~(34)~~ (35) "Milk tank truck driver" means a person who transports raw or pasteurized milk products to or from a:

- (A) milk plant;

- (B) receiving station; or  
(C) transfer station.
- ~~(35)~~ **(36)** "New producer" means any milk producer who has not sold raw milk within a period of ninety (90) days before the delivery in question.
- ~~(36)~~ **(37)** "Producer" means milk producer as defined in the PMO.
- ~~(37)~~ **(38)** "Producer's marketing organization" means a milk producer organization that manages the marketing of a milk producer's raw milk.
- ~~(38)~~ **(39)** "Reconstituted or recombined milk and milk products" means milk or milk products defined in this rule that result from the reconstituting or recombining of milk constituents with potable water when appropriate.
- ~~(39)~~ **(40)** "Regulatory agency" means the board.
- ~~(40)~~ **(41)** "Sanitization" means the application of any effective method or substance to surfaces that are clean to destroy pathogens and other microorganisms as far as is practical without adversely affecting the following:
- (A) Equipment.
  - (B) Milk products.
  - (C) The health of consumers.
- ~~(41)~~ **(42)** "Sheep milk" means the normal lacteal secretion, practically free of colostrum, obtained by the complete milking of one (1) or more healthy sheep.
- ~~(42)~~ **(43)** "Standard methods" means the "Standard Methods for the Examination of Dairy Products", published by the American Public Health Association.
- ~~(43)~~ **(44)** "State veterinarian" means the state veterinarian appointed under [IC 15-17-4](#) or an official designee.
- (45) "Ungraded milk" means all milk that is not:**
- (A) required by [IC 15-18](#) to be produced under a Grade A permit; or**
  - (B) manufacturing grade milk.**
- ~~(44)~~ **(46)** "Uniform Indiana Food, Drug, and Cosmetic Act" means the Uniform Food, Drug, and Cosmetic Act at [IC 16-42-1](#) through [IC 16-42-4](#).

(b) Where a definition in a matter incorporated by reference conflicts with a definition in this section, the express provisions of this section shall control.

*(Indiana State Board of Animal Health; [345 IAC 8-2-1.1](#); filed Apr 17, 1998, 9:00 a.m.: 21 IR 3343; errata filed Aug 13, 1998, 1:16 p.m.: 22 IR 125; readopted filed May 2, 2001, 1:45 p.m.: 24 IR 2895; filed Sep 27, 2002, 2:40 p.m.: 26 IR 329; filed Jul 18, 2005, 1:00 p.m.: 28 IR 3557; readopted filed May 9, 2007, 3:16 p.m.: [20070516-IR-345070037RFA](#); errata filed Oct 3, 2008, 3:30 p.m.: [20081022-IR-345080767ACA](#); filed Dec 10, 2010, 10:42 a.m.: [20110105-IR-345100123FRA](#); filed Dec 4, 2014, 1:59 p.m.: [20141224-IR-345140199FRA](#); filed Dec 7, 2016, 9:26 a.m.: [20170104-IR-345160222FRA](#); filed Feb 23, 2021, 1:10 p.m.: [20210324-IR-345200476FRA](#))*

SECTION 2. [345 IAC 8-2-2.1](#) IS AMENDED TO READ AS FOLLOWS:

**[345 IAC 8-2-2.1](#) Manufacturing grade milk plant; construction; operation; sanitation**

**Authority:** [IC 15-17-3-21](#)

**Affected:** [IC 15-17-2](#); [IC 15-18-1](#)

Sec. 2.1. (a) Except as provided in section 2.2 of this rule, a manufacturing grade milk plant shall meet the requirements in this section.

**(b) The board incorporates by reference as a rule of the board the following parts of the Grade A Pasteurized Milk Ordinance, United States Department of Health and Human Services, Public Health Service, Food and Drug Administration (2019 revision), referred to as the PMO for regulation of the production, transportation, processing, handling, sampling, examination, grading, labeling, and sale of all manufacturing grade milk products in the state:**

- (1) Section 1. Definitions.**
- (2) Section 4. Labeling. However, requirements in this Section that specifically apply to the labeling of Grade A milk products are not incorporated.**
- (3) Item 1p. Floors – Construction.**
- (4) Item 2p. Walls and Ceilings – Construction.**
- (5) Item 3p. Doors and Windows.**
- (6) Item 4p. Lighting and Ventilation.**
- (7) Item 5p. Separate Rooms.**

- (8) Item 6p. Toilet-Sewage Disposal Facilities.
- (9) Item 7p. Water Supply.
- (10) Item 8p. Handwashing Facilities.
- (11) Item 9p. Milk Plant Cleanliness.
- (12) Item 10p. Sanitary Piping.
- (13) Item 11p. Construction and Repair of Containers and Equipment. However, requirements in the Section that specifically apply to the containers and equipment for Grade A milk products are not incorporated.
- (14) Item 12p. Cleaning and Sanitizing of Containers and Equipment.
- (15) Item 13p. Storage of Cleaned Containers and Equipment.
- (16) Item 14p. Storage of Single-Service Articles, Utensils, and Materials.
- (17) Item 15p. Protection from Contamination.
- (18) Item 16p. Pasteurization, including the procedures for the following:
  - (A) Batch pasteurization.
  - (B) High-temperature-short-time (HTST) continuous flow pasteurization.
  - (C) Pasteurizers employing regenerative heating.
  - (D) Pasteurization records, equipment tests, and examinations.However, this Item does not apply to raw milk cheeses.
- (19) Item 17p. Cooling of Milk and/or Milk Products. However, this Item does not apply to the following products:
  - (A) Ice cream.
  - (B) Raw milk cheeses during the sixty (60) day aging process.
  - (C) Manufacturing grade raw milk received for processing and governed by the temperature and storage requirements set forth at [IC 15-18-1-19](#).
- (20) Item 18p. Bottling, Packaging and Container Filling must occur:
  - (A) at the place of pasteurization in a sanitary manner; and
  - (B) in accordance with the standards for mechanical equipment set forth in this Item.However, if the plant does not use approved mechanical equipment, then the requirements in clause (B) do not apply.
- (21) Item 19p. Capping, Container Closure, and Sealing and Dry Milk Product Storage must occur:
  - (A) at the place of pasteurization in a sanitary manner; and
  - (B) in accordance with the standards for mechanical equipment set forth in this Item.However, if the plant does not use approved mechanical equipment, then the requirements of clause (B) do not apply.
- (22) Item 20p. Personnel – Cleanliness and Practices.
- (23) Item 21p. Vehicles.
- (24) Item 22p. Surroundings.
- (25) Appendix D. Standards for Water Sources.
- (26) Appendix F. Cleaning and Sanitization.
- (27) Appendix G. Chemical and Bacteriological Tests.
- (28) Appendix H. Pasteurization Equipment and Procedures and Other Equipment.
- (29) Appendix I. Pasteurization Equipment and Controls – Tests.
- (30) Appendix L. Applicable Regulations, Standards of Identity for Milk and Milk Products.
- (31) Appendix N. Drug Residue Testing and Farm Surveillance.
- (32) Appendix R. Determination of Time/Temperature Control for Safety Milk and/or Milk Products.
- (33) Appendix S. Aseptic Processing and Packaging Program and Retort Processed after Packaging Program.

~~(b)~~ (c) A manufacturing grade milk plant must follow and the board incorporates by reference the following Subparts of 21 CFR 117 as a rule of the board:

- (1) Subpart A – General Provisions. However, the following provisions are not incorporated:
  - (A) 21 CFR 117.5(b) through 21 CFR 117.5(j).
  - (B) 21 CFR 117.8.
- (2) Subpart B – Good Manufacturing Practices.
- (3) Subpart C – Hazard Analysis and Risk Based Preventive Controls.
- (4) Subpart D – Modified Requirements, except 21 CFR 117.201 is not incorporated.
- (5) Subpart F – Requirements Applying to Records that must be Established and Maintained. However, the following provisions are not incorporated:
  - (A) 21 CFR 117.320.
  - (B) 21 CFR 117.325.



(6) Subpart G – Supply Chain Program.

(e) **(d)** Milk received for pasteurization, processing, or packaging by a manufacturing grade milk plant must be obtained from one (1) of the following sources:

- (1) A dairy farm within the state that holds a valid Grade A or manufacturing grade permit issued under this article.
- (2) A dairy farm outside the state that holds a valid Grade A or manufacturing grade permit in the state of origin.
- (3) Any other source of milk that has been approved by the state veterinarian based upon a finding that the source meets the standards of this article.

**(e)** Where matters incorporated by reference in this section conflict with provisions of this article, [IC 15-17-2](#), or [IC 15-18-1](#), the express provisions of this article and the Indiana Code shall control.

**(f)** Frozen desserts in the manufacturer's unbroken package shall have a bacterial plate count of not more than thirty thousand (30,000) per gram and a coliform count of not more than ten (10) per gram. The bacterial plate count shall be considered satisfactory when the results of not more than two (2) of the last four (4) consecutive samples taken on separate days exceed thirty thousand (30,000) per gram. The coliform count shall be considered satisfactory when the results of not more than one (1) of four (4) consecutive samples taken upon separate days exceed ten (10) per gram.

*(Indiana State Board of Animal Health; [345 IAC 8-2-2.1](#); filed Dec 7, 2016, 9:26 a.m.: [20170104-IR-345160222FRA](#); filed Jun 13, 2018, 2:27 p.m.: [20180711-IR-345170566FRA](#), eff Sep 17, 2018; filed Feb 23, 2021, 1:10 p.m.: [20210324-IR-345200476FRA](#))*

SECTION 3. [345 IAC 8-2-3](#) IS AMENDED TO READ AS FOLLOWS:

**[345 IAC 8-2-3](#) Manufacturing grade dairy farms; construction; operation; sanitation**

**Authority:** [IC 15-17-3-21](#); [IC 15-18-1-14](#)

**Affected:** [IC 15-18-1-18](#)

Sec. 3. (a) Manufacturing grade dairy farms must meet the following requirements:

- (1) All dairy cattle and goats must comply with [IC 15-18-1-18](#) and current board laws relating to the control and eradication of tuberculosis and brucellosis.
- (2) Cows, sheep, or goats that show evidence of the secretion of abnormal milk in any quarter shall be milked last or in separate equipment and the milk shall be discarded. Cows, sheep, or goats that have been treated with or that have consumed chemical, medicinal, or radioactive agents that:
  - (A) are capable of being secreted in the milk; and
  - (B) in the judgment of the state veterinarian may be deleterious to human health;shall be milked last or with separate equipment and the milk disposed of as the state veterinarian may direct.

(b) The area where milking is conducted must meet the following requirements:

- (1) The milking area shall be separate from horses, calves, bulls, or maternity pens or stalls, and feed rooms or silos. The milking area shall be of adequate size.
- (2) The milking area shall be provided with the following:
  - (A) Natural lighting or artificial lighting, or a combination of both, to furnish at least ten (10) foot-candles of light in work areas.
  - (B) Ventilation.
  - (C) Impervious floors and floor gutters.
- (3) Floors, walls, and ceilings shall be constructed of a smooth, easily cleanable material that is light-colored or painted a light color and kept clean and in good repair. The outside of any milking equipment located in the milking area shall be kept clean. Surcingle, antikickers, and milk stools shall be kept clean and stored above the floor.
- (4) No swine or fowl shall be allowed in the milking area.

(c) Any person who is milking shall have clean hands and clothing. Cows' flanks, udders, and tails shall be clean at time of milking. Udders shall be washed clean, sanitized, and dried immediately prior to milking. All milk shall be strained in the milkhouse unless a straining receptacle:

- (1) protected from splash;
- (2) raised above the floor; and
- (3) provided with a self-closing lid;

is provided. Milk being strained or carried to the milkhouse must be protected from contamination.

(d) A milkhouse of adequate size and conveniently located shall be provided for the handling, straining, and cooling of milk, and for the washing, handling, and storing of utensils and equipment. The milkhouse must meet the following requirements:

- (1) A minimum of twenty (20) foot-candles of light from natural or artificial lighting, or a combination of both, shall be provided at all work areas.
  - (2) Ventilation shall be provided to minimize odors and condensation.
  - (3) Floors shall be impervious and graded to drain.
  - (4) Walls and ceilings shall be constructed of a smooth, easily cleanable material that is light-colored or painted a light color.
  - (5) Vats shall be provided for washing and rinsing of utensils and equipment. Hot water shall be available, and water must be readily accessible.
  - (6) The construction of the milkhouse shall be sufficiently tight to prevent the entrance of rodents and flies. Flies shall be kept out of the milkhouse. Outer doors shall be self-closing.
  - (7) Liquid milkhouse wastes shall be disposed of in a manner that will preclude insect breeding or contamination of surface or underground water.
  - (8) The milk product contact surfaces of all multi-use containers, equipment, and utensils shall be:
    - (A) cleaned after each usage; and
    - (B) sanitized before each usage.
  - (9) Equipment and utensils shall be stored and drained completely so as to prevent contamination.
  - (10) Strainer pads, sock filters, and similar single-service articles are stored in a clean, tight cabinet or container.
  - (11) Multi-use milk contact equipment:
    - (A) must be made of smooth, nonabsorbent, and nontoxic materials; and
    - (B) shall be so constructed and maintained so as to be easily cleaned.
- Single-service articles shall not be reused.

(e) Only pesticides approved by the board are to be used in the milkhouse. Pesticides not approved for use in the milkhouse shall not be stored in the milkhouse.

(f) Medicinals, antibiotics, and approved pesticides may be kept in the milkhouse only in separate tight cabinets or containers provided exclusively for their use. Pesticides must be stored in separate cabinets from animal drugs. Animal drugs must be properly labeled, and lactating drugs must be segregated from nonlactating drugs. Drugs not approved for use in dairy animals must not be used except in compliance with state and federal law.

(g) The floors, walls, ceilings, and surfaces of all milkhouse equipment and appurtenances shall be clean. The milkhouse shall be used for milking operations only, and only those articles directly related to milkhouse activities shall be permitted in the milkhouse. Trash, animals, and fowl shall be kept out of the milkhouse.

**(h) Ungraded milk shall not be:**

- (1) stored in the permitted bulk tank with milk for graded purposes; or**
- (2) harvested using common equipment unless:**
  - (A) it is harvested after all graded milk; and**
  - (B) the equipment is completely washed prior to subsequent milkings.**

~~(h)~~ **(i)** Farms with bulk milk coolers shall provide a suitable hose port opening with a tight self-closing cover. The area under the outside of the hose port shall be surfaced with a material that will prevent soiling of the milk transfer hose.

~~(h)~~ **(j)** Manure shall be handled in a manner that controls insect breeding. Manure piles or storage areas shall be inaccessible to cows. Cowyards, free stalls, and loafing areas shall be kept clean. Surroundings shall be neat, clean, and free of conditions that could result in rodent harborages or insect attractants and breeding areas. Dead livestock shall be properly disposed of promptly in accordance with requirements of the board.

~~(j)~~ **(k)** The water supply for the milkhouse and for washing and sanitizing of utensils shall be:

- (1) properly located, constructed, and operated;
- (2) adequate;
- (3) easily accessible; and
- (4) of a safe, sanitary quality.

~~(k)~~ **(l)** Every dairy farm shall be provided with a sanitary toilet conveniently located and accessible to those persons performing the milking operation. The toilet shall be constructed and maintained so that the waste:

- (1) is inaccessible to flies; and
- (2) does not pollute the surface soil or contaminate any water supply.

~~(l)~~ **(m)** Raw milk from manufacturing grade dairy farms shall not be stored on such dairy farms in cans for more than forty-eight (48) hours or in a farm bulk tank for more than seventy-two (72) hours. The milk must be cooled to sixty (60) degrees Fahrenheit and maintained at that temperature at the point of origin unless delivered to a milk plant, receiving station, or transfer station within two (2) hours after milking. Auxiliary can milk storage shall not be permitted on dairy farms equipped for bulk milk cooling and storage.

~~(m)~~ **(n)** Manufacturing grade raw milk must undergo the following tests and meet the following requirements, and official test results for bacteria and somatic cell count tests must be reported to the board within ten (10) business days of the sample being taken:

- (1) In addition to drug residue screening of manufacturing grade milk delivered for processing as required under [345 IAC 8-4-1](#), at least four (4) times in any six (6) month period at irregular intervals, plants receiving manufacturing grade raw milk shall test a commingled sample of each producer's milk for drug residues. Positive test results must be reported to the board immediately. The procedures and penalties in [345 IAC 8-4-1](#) apply when drug residues are found in a producer's milk.
- (2) Bacteriological, somatic cell, and drug residue standards shall be as follows:
  - (A) Manufacturing grade milk shall meet the following standards:
    - (i) The milk will be classified as "acceptable" if a laboratory examination to determine the bacterial estimate using the standard plate count, direct microscopic count, plate loop count, or other official approved methods indicates the presence of not more than five hundred thousand (500,000) bacteria per milliliter.
    - (ii) The somatic cell count, using the direct microscopic somatic cell count or other official laboratory test, shall be not more than seven hundred fifty thousand (750,000) per milliliter. However, the somatic cell count for goat's milk may not be more than one million five hundred thousand (1,500,000) cells per milliliter.
    - (iii) The milk shall not test positive for drug residues.
  - (B) Milk not meeting the standards in clause (A)(i) or (A)(ii) shall be designated as undergrade.
  - (C) Milk that does not meet the standard in clause (A)(iii) shall not be used for human food. It may be used for animal food if it is diverted in accordance with rules of the board.
  - (D) After the board designates a producer's milk sample undergrade, the following shall apply:
    - (i) The board will notify the buyer and the buyer will notify the producer of milk designated undergrade.
    - (ii) Additional samples of the producer's milk shall be tested and classified by the buyer at least monthly with the buyer immediately notifying the producer of the results.
- (3) Plants receiving manufacturing grade milk shall run an official approved test on a commingled sample of each producer's milk for somatic cell count and bacteria count four (4) times in any six (6) month period. Confirmatory tests using an approved method shall be performed when the test method utilized requires confirmatory tests. Whenever the somatic cell count or bacteria test indicates undergrade milk, the procedure in subdivision (4) shall be applied.
- (4) The following apply when milk is determined to be undergrade because of a somatic cell count or bacteria count in excess of the limits set forth in this section:
  - (A) A notice shall be sent to the producer notifying him or her of the violation.
  - (B) Whenever two (2) of the last four (4) consecutive tests exceed the limit for somatic cells or bacteria as the case may be, a warning notice shall be sent to the producer. The notice shall remain in effect as long as two (2) of the last four (4) consecutive samples exceed the limit. A check sample shall be taken after a lapse of three (3) days and within fourteen (14) days of the warning notice. If this sample also indicates a violation, that milk shall be excluded from the market.
  - (C) Whenever three (3) out of the last (5) consecutive tests exceed the limit for somatic cells or bacteria as the case may be, the farm permit will be suspended until an official sample tests below the limit and the farm passes an inspection by the board.

All milk quality tests shall be made in accordance with methods described in the latest edition of Standard



Methods for the Examination of Dairy Products or the Official Methods of Analyses of the Association of Analytical Chemists. Samples shall be analyzed at a laboratory approved by the state veterinarian.

(5) An examination shall be made on the first shipment of milk from producers shipping milk to a plant for the first time, or from a producer who has not shipped milk for a period of ninety (90) days. The milk shall meet all quality standards defined by this rule. Thereafter, the milk shall be tested in accordance with the procedure established for regular shippers.

(6) The milk of a producer that has been excluded due to failure to meet quality standards shall not be accepted by another plant until quality standards are met.

~~(n)~~ (o) Before milkhouses, milking barns, stables, or parlors regulated under this rule are constructed or extensively altered, construction plans shall be submitted to the board for written approval before work is begun.

(Indiana State Board of Animal Health; HDP 86 Rule 13, Sec 3; filed Apr 26, 1979, 12:00 p.m.: 2 IR 693, eff one hundred twenty (120) days after filing with secretary of state; filed Jan 29, 1986, 3:10 p.m.: 9 IR 1315; filed Apr 17, 1998, 9:00 a.m.: 21 IR 3347; errata filed Aug 13, 1998, 1:13 p.m.: 22 IR 125; errata filed Aug 13, 1998, 1:16 p.m.: 22 IR 126; readopted filed May 2, 2001, 1:45 p.m.: 24 IR 2895; filed Sep 27, 2002, 2:40 p.m.: 26 IR 335; readopted filed May 9, 2007, 3:16 p.m.: [20070516-IR-345070037RFA](#); errata filed Oct 3, 2008, 3:30 p.m.: [20081022-IR-345080767ACA](#); filed Dec 10, 2010, 10:42 a.m.: [20110105-IR-345100123FRA](#), eff Jan 1, 2011 [[IC 4-22-2-36](#) suspends the effectiveness of a rule document for 30 days after filing with the Publisher. LSA Document #10-123 was filed Dec 10, 2010.]; filed Dec 4, 2014, 1:59 p.m.: [20141224-IR-345140199FRA](#); readopted filed Jul 14, 2020, 1:42 p.m.: [20200812-IR-345200230RFA](#); filed Feb 23, 2021, 1:10 p.m.: [20210324-IR-345200476FRA](#)) NOTE: Transferred from the Indiana State Department of Health ([410 IAC 8-13-3](#)) to the Indiana State Board of Animal Health ([345 IAC 8-2-3](#)) by P.L. 137-1996, SECTION 76, effective July 1, 1996.

SECTION 4. [345 IAC 8-3-1](#) IS AMENDED TO READ AS FOLLOWS:

#### [345 IAC 8-3-1](#) Incorporation by reference; standards

**Authority:** [IC 15-17-3-19](#); [IC 15-17-3-21](#); [IC 15-18-1-14](#)

**Affected:** [IC 15-17-2](#); [IC 15-18-1](#)

Sec. 1. (a) The board incorporates by reference as a rule of the board the Grade A Pasteurized Milk Ordinance, United States Department of Health and Human Services, Public Health Service, Food and Drug Administration (2017 (2019 revision), referred to as the PMO for regulation of the production, transportation, processing, handling, sampling, examination, grading, labeling, and sale of all Grade A milk and milk products in the state. Except where specifically excluded, the board intends to incorporate all parts of the PMO to include all of the administrative procedures and the appendixes. However, the following parts of the PMO are not incorporated by reference as a rule of the board:

- (1) Section 16 on penalties.
- (2) Section 17 on repeal and date of effect.
- (3) Appendix P.

The board intends to incorporate the footnoted language in the PMO regarding cottage cheese that will apply to any person producing Grade A cottage cheese and Grade A dry curd cottage cheese. However, a person may produce cottage cheese and dry curd cottage cheese as a manufacturing grade milk product (not Grade A) by complying with the manufacturing grade milk products requirements under this article. References in the PMO to the regulatory agency shall mean and refer to the board.

(b) The board will utilize the latest edition of the following documents when interpreting and implementing the provisions of the PMO, this article, and [IC 15-18](#):

- (1) The following National Conference on Interstate Milk Shipments model documents:
  - (A) Procedures Governing the Cooperative State-Public Health Service / Food and Drug Administration Program of the National Conference on Interstate Shipments.
  - (B) Methods of Making Sanitation Ratings of Milk Shippers.
  - (C) Evaluation of Milk Laboratories.
- (2) The following sets of documents issued by the United States Food and Drug Administration, Milk Safety Branch:
  - (A) Memoranda of Interpretation (M-a series documents).
  - (B) Memoranda of Milk Ordinance Equipment Compliance (M-b series documents).
  - (C) Memoranda of Information (M-I series documents).

(c) The board adopts by reference the general provisions relating to food standards set forth by the United States Food and Drug Administration in 21 CFR 130.8, 21 CFR 130.9, 21 CFR 130.10, and 21 CFR 130.11, in effect on April 1, 2017: **2020**.

(d) The board adopts by reference the definitions and standards of identity for milk and milk products set forth by the United States Food and Drug Administration in 21 CFR 131.3 et seq., titled "Part 131—Milk and Cream", in effect on April 1, 2017: **2020**. Milk and milk products must conform to these standards.

(e) The board adopts by reference the definitions and standards of identity for cheeses and related cheese products set forth by the United States Food and Drug Administration in 21 CFR 133.3 et seq., titled "Part 133—Cheeses and Related Cheese Products", in effect on April 1, 2017: **2020**. Cheese and cheese products must conform to these standards.

(f) The board adopts by reference the definitions and standards of identity for frozen desserts set forth by the United States Food and Drug Administration in 21 CFR 135.3 et seq., titled "Part 135—Frozen Desserts", in effect on April 1, 2017: **2020**. Frozen desserts must conform to these standards.

(g) The board adopts by reference the current good manufacturing practices for manufacturing, packing, or holding human food set forth by the United States Food and Drug Administration in 21 CFR 113, in effect on April 1, 2017: **2020**. The criteria and definitions in 21 CFR 113 and this rule shall apply in determining whether a food is adulterated under [IC 15-18-1](#) in that the food has been manufactured under such conditions that it is unfit for human food or the food has been prepared, packed, or held under unsanitary conditions under which the product may:

- (1) become contaminated with filth; or
- (2) have been made injurious to health.

(h) The board adopts by reference as a rule of the board the food labeling requirements set forth by the United States Food and Drug Administration in 21 CFR 101, but not including Subpart C, in effect on April 1, 2017: **2020**.

(i) The board incorporates by reference into this rule the definitions set forth in [IC 15-17-2](#) and the matters set forth in [IC 15-18-1](#).

(j) Where the matters incorporated by reference in this section conflict with provisions of this article, [IC 15-17-2](#), or [IC 15-18-1](#), the express provisions of this article and the Indiana Code shall control.

(k) Incorporated documents are available for public inspection at the board. Copies of incorporated documents and interpreting and implementing documents may be obtained from the Food and Drug Administration, Milk Safety Branch website, the U.S. Government ~~Printing~~ **Publishing** Office website, or by sending a written request to the board.

*(Indiana State Board of Animal Health; [345 IAC 8-3-1](#); emergency rule filed Jan 27, 1994, 5:00 p.m.: 17 IR 1223, eff Feb 1, 1994; filed Apr 17, 1998, 9:00 a.m.: 21 IR 3354; errata filed Aug 13, 1998, 1:16 p.m.: 22 IR 126; readopted filed May 2, 2001, 1:45 p.m.: 24 IR 2895; filed Sep 27, 2002, 2:40 p.m.: 26 IR 340; filed Jul 18, 2005, 1:00 p.m.: 28 IR 3564; readopted filed May 9, 2007, 3:16 p.m.: [20070516-IR-345070037RFA](#); filed Dec 18, 2007, 3:45 p.m.: [20080116-IR-345070296FRA](#); filed Aug 11, 2008, 3:37 p.m.: [20080910-IR-345080125FRA](#); errata filed Oct 3, 2008, 3:30 p.m.: [20081022-IR-345080767ACA](#); filed Dec 10, 2010, 10:42 a.m.: [20110105-IR-345100123FRA](#); filed Sep 11, 2012, 2:35 p.m.: [20121010-IR-345120107FRA](#); filed Dec 4, 2014, 1:59 p.m.: [20141224-IR-345140199FRA](#); filed Dec 7, 2016, 9:26 a.m.: [20170104-IR-345160222FRA](#); filed Jun 13, 2018, 2:27 p.m.: [20180711-IR-345170566FRA](#), eff Sep 17, 2018; filed Feb 23, 2021, 1:10 p.m.: [20210324-IR-345200476FRA](#)) NOTE: Transferred from the Indiana State Department of Health ([410 IAC 8-14-8.1](#)) to the Indiana State Board of Animal Health ([345 IAC 8-3-1](#)) by P.L. 137-1996, SECTION 76, effective July 1, 1996.*

SECTION 5. [345 IAC 8-3-2](#) IS AMENDED TO READ AS FOLLOWS:

#### **[345 IAC 8-3-2](#) Grade A milk production and storage**

Sec. 2. The following are required to hold a Grade A dairy farm permit:

(1) Milk that is produced or processed must meet the chemical, bacteriological, and temperature standards in Section 7 and Table 1 of the PMO adopted by reference in section 1 of this rule.

(2) The farm must meet the sanitation, construction, operation, and other standards in the provisions of the Pasteurized Milk Ordinance adopted by reference in section 1 of this rule, including the following:

(A) Section 7, "Standards for Grade "A" Raw Milk For Pasteurization, Ultra-Pasteurization, or Aseptic Processing and Packaging", Items 1r through 19r.

(B) Appendix C, "Dairy Farm Construction Standards; Milk Production".

(C) Appendix D, "Standards for Water Sources".

(D) Appendix F, "Sanitization".

(E) A farm utilizing an automatic milking installation (AMI) must comply with Appendix Q.

(3) The animals on the farm must meet the animal health requirements in [IC 15-18-1-18](#) and Section 8 of the Pasteurized Milk Ordinance adopted by reference in section 1 of this rule.

(4) The "administrative procedures" set forth in the Pasteurized Milk Ordinance adopted by reference in section 1 of this rule shall be followed in implementing the standards required in this section.

(5) Before:

(A) milkhouses;

(B) milking barns;

(C) stables; or

(D) parlors;

regulated under this rule are constructed or extensively altered, construction plans shall be submitted to the state veterinarian for written approval before work is begun.

(6) Raw milk for pasteurization shall not be stored:

(A) on a dairy farm for more than forty-eight (48) hours; however, sheep and goat milk may be stored on a dairy farm for up to seven (7) days in accordance with the procedures in the Grade A Pasteurized Milk Ordinance; and

(B) outside a farm bulk milk tank.

(7) Agitation and refrigeration of all farm bulk milk cooling and holding tanks shall be automatically controlled with automatic controls that will maintain mixed milk temperature between thirty-two (32) degrees Fahrenheit and forty-five (45) degrees Fahrenheit and an interval timer that will activate agitation of the milk for a minimum period of two (2) minutes in every sixty (60) minute interval.

(8) A farm's milkhouse bulk tank may only be used for collection and storage of raw milk for pasteurization. A farm's milkhouse bulk tank may be converted to a raw milk storage vessel holding commingled raw milk for pasteurization as follows:

(A) Once the final milking has been completed and before processing, a bulk tank sample of the farm's milk supply must be collected by a permitted hauler/sampler for quality and drug residue testing.

(B) The collected sample must be tested and meet the Grade A quality and drug residue standards.

(C) Raw milk from other bulk tank units (BTU) may only be commingled after milk quality and drug residue samples have been collected and the milk from each BTU meets Grade A standards.

(D) Before untested milk may be added to the milkhouse bulk tank, the bulk tank must be emptied, cleaned, and sanitized in accordance with the Grade A Pasteurized Milk Ordinance (PMO). Untested milk shall not be added or commingled with tested milk in the farm milkhouse bulk tank.

~~(9) A farm producing raw milk for pasteurization must protect the milk in the bulk tank from cross contamination when that milk is being used for purposes in addition to sales as Grade A milk. When milk is being removed from the bulk tank, it shall be removed in the following order:~~

~~(A) Grade A milk for pasteurization.~~

~~(B) Milk for manufacturing.~~

~~(C) Milk for animal feed.~~

~~(D) Milk for personal consumption.~~

~~Once all of the milk has been removed, the bulk tank shall be cleaned and sanitized prior to the next milking.~~

**(9) Ungraded milk shall not be:**

**(A) stored in the permitted bulk tank with milk for graded purposes; or**

**(B) harvested using common equipment unless:**

**(i) it is harvested after all graded milk; and**

**(ii) the equipment is completely washed prior to subsequent milkings.**

*(Indiana State Board of Animal Health; [345 IAC 8-3-2](#); emergency rule filed Jan 27, 1994, 5:00 p.m.: 17 IR 1224, eff Feb 1, 1994; filed Apr 17, 1998, 9:00 a.m.: 21 IR 3355; readopted filed May 2, 2001, 1:45 p.m.: 24 IR 2895;*

filed Sep 27, 2002, 2:40 p.m.: 26 IR 341; filed Jul 18, 2005, 1:00 p.m.: 28 IR 3565; readopted filed May 9, 2007, 3:16 p.m.: [20070516-IR-345070037RFA](#); errata filed Oct 3, 2008, 3:30 p.m.: [20081022-IR-345080767ACA](#); filed Sep 11, 2012, 2:35 p.m.: [20121010-IR-345120107FRA](#); filed Dec 4, 2014, 1:59 p.m.: [20141224-IR-345140199FRA](#); filed Dec 7, 2016, 9:26 a.m.: [20170104-IR-345160222FRA](#); filed Feb 23, 2021, 1:10 p.m.: [20210324-IR-345200476FRA](#)) NOTE: Transferred from the Indiana State Department of Health ([410 IAC 8-14-8.2](#)) to the Indiana State Board of Animal Health ([345 IAC 8-3-2](#)) by P.L.137-1996, SECTION 76, effective July 1, 1996.

LSA Document #20-476(F)

Notice of Intent: [20200923-IR-345200476NIA](#)

Proposed Rule: [20201104-IR-345200476PRA](#)

Hearing Held: January 26, 2021

Approved by Attorney General: February 18, 2021

Approved by Governor: February 23, 2021

Filed with Publisher: February 23, 2021, 1:10 p.m.

Documents Incorporated by Reference: Grade "A" Pasteurized Milk Ordinance, 2019 Revision; 21 CFR 101; 21 CFR 113; 21 CFR 117; 21 CFR 130; 21 CFR 131; 21 CFR 133; 21 CFR 135, all in effect April 1, 2020

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Posted: 03/24/2021 by Legislative Services Agency

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